REMARKS

The above-captioned patent application has been carefully reviewed in light of the non-final Office Action to which this Amendment is responsive. Claims 3, 6, 7, 11, 14-22 and 56-59 have been amended in an effort to further clarify and distinctly describe the present invention. Claims 2, 4, 5, 55, 60 and 61 have been canceled and new Claims 62-71 have been added. To that end, it is believed that no new matter has been added.

The Examiner has rejected all pending Claims 2-22 and 55-61 on the basis of certain prior art and also under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Applicants herein respectfully request reconsideration based on the amended claims and the following discussion.

Applicants gratefully acknowledge the interview extended to Applicants' representative, Peter J. Bilinski, by Examiner Lyle Alexander on June 23, 2005. The subject matter of the interview is included in the text of this response.

Prior to a discussion of any of the rejections, Applicants would like to again briefly summarize the novel contributions made by the present invention. That is, an incubator is herein provided for use in a clinical analyzer. As described with reference to Figs. 3-12, the incubator according to one version includes respective first and second rings that are concentrically situated relative to each other. Each of the inner and outer rings includes respective first and second pluralities of circumferentially disposed sample element receiving areas. According to the embodiment described in the above-captioned application, the inner ring includes a pair of radially adjacent sample receiving area arrays and the outer ring includes a single circumferential array of sample element receiving areas. As such, the first and second pluralities of sample element receiving areas are radially adjacent to one another and are further provided on a common horizontal plane.

The inner and outer rings are rotatably driven, such as by a belt drive, to enable rotation about their axes, in either a clockwise or counterclockwise direction along the common horizontal plane. Moreover, the inner and outer rings can be driven (e.g., rotated) independently from one another. Each of the rings are provided on the common horizontal plane such that at least one shuttle mechanism provided adjacent to the inner or the outer rings of the incubator can be utilized selectively to move sample elements (such as, for example, dry slide elements) in a radial direction between the sample element receiving areas of the outer ring and the inner ring.

More particularly and according to the present invention, the at least one shuttle mechanism allows any number of sample elements to be shifted within the confines of the incubator between adjacent planar sample element receiving areas. As such, separately disposed sample element shuttle mechanisms disposed at discrete circumferential locations or positions relative to the inner and/or outer ring permit any number of sample elements to be selectively shifted between different radial positions in either the inner and outer rings. This selective shifting of sample elements provides an advantage in that greater throughput is provided for the clinical analyzer to which the incubator is used as well as a more efficient means for the scheduling of test events.

For example, one shuttle mechanism can be used to allocate a sample element that has been loaded into the incubator in the outer ring wherein the sample element can be rotated a number of positions (N) about the axis of the ring and then the same or an circumferentially adjacent shuttle mechanism can be used to push the sample element into the inner ring, freeing the adjacent sample element receiving area of the inner ring so as to allow the receiving area to load another metered sample element and permitting the shuttled sample element to be moved (e.g., rotated) by the inner ring until the sample element is moved into alignment with a read station. Alternately, other sample elements can remain on the exterior or the outer ring, depending, for example, on the type of sample element used, the forms of tests required, etc.

As noted, there are a number of advantages in providing the above features and permitting planar radial and notational movement of the sample elements in the manner herein described. By providing a number of sample elements having different chemistries and having different test protocols, there are also correspondingly different incubation requirements (cycle times). Using the present incubator, a first sample element can be shuttled into the outer ring for potentiometric testing and a second sample element can then be shuttled into the incubator for colorimetric testing upon rotation of the outer ring to a circumferentially adjacent sample element receiving area. Subsequent rotation of the outer ring enables the second sample element to be relocated, such as by the same or another shuttle mechanism, between the radially adjacent sample receiving area of the outer ring planarly and a corresponding receiving area of the inner ring, while the potentiometric (first) element can remain in the outer ring. In the meantime, additional sample elements can be loaded into the incubator into "freed up" or empty sample receiving areas of the inner ring, effectively increasing throughput. Additionally, an IR wash or other module can be added to the interior of the inner ring, providing further versatility with another radially adjacent shuttle mechanism that can be used to move sample elements into and out of the module and between radially adjacent sample receiving areas of the inner and outer rings as the inner and outer rings of the incubator are caused to rotate about their respective axes.

A greater number of sample elements can be loaded into the incubator housing at any one time and handled appropriately wherein the synchronization of the ring/rotor assemblies can be preset, for example, by an offsetting to permit efficient transfer of sample elements between the concentric rotor assemblies and therefore to efficiently maintain and improve the test schedule of the clinical analyzer.

In order to better clarify and distinctly point out the above-noted features, Applicants have canceled independent Claims 60 and 61 and replaced these claims with new Claims 62 and 63. Claim 62, as amended, includes the features of original Claims 2, 4 and 5, now canceled, and more distinctly and positively recites the

structural aspects of the incubator depicted in Figs. 3-12 in clearer detail. To that end, Claim 62 now more clearly recites the structural relationship of the inner and outer rings of the incubator, including the rotatability of each. This claim now also positively recites the nature of the radial and planar orientation of the adjacent sample element receiving areas of the inner and outer rings of the incubator and their relative positioning in a common horizontal plane and the provision of at least one drive mechanism that is used to move at least one sample element between the inner and outer rings of the incubator in a radial direction along the common horizontal plane in order to improve the throughput of the incubator. All of the movements (rotation, radial) are made herein exclusively in a common horizontal plane.

Claim 63, as amended, includes the features of original Claims 54 and 55, now canceled, and recites a method for incubating a plurality of sample elements using an incubator having an inner and outer ring, each of the rings including first and second pluralities of circumferentially disposed sample element receiving areas that are radially adjacent to one another and further disposed on a common horizontal plane. Moreover, this claim recites a method including the steps of loading at least one sample element into an empty sample element receiving area of said one of said inner and outer rings at a first radial position, rotating said inner and outer rings to a second predetermined radial position, and radially moving the at least one sample element between the inner and outer rings at the second radial position along the common horizontal plane, thereby effectively improving the throughput of the incubator.

It is believed the above claim amendments render the outstanding first and second paragraph Section 112 rejections moot. Support is clearly provided for each of the above claim amendments with regard to the recitation of the inner and outer rings and the two drive mechanisms that move the inner and outer rings of the incubator to enable rotation and the shuttle mechanisms to enable radial disposition/loading/unloading of sample elements between adjacent radial positions of the inner and outer rings. Moreover, each of the rotational and radial movements

are made exclusively along a common horizontal plane. Therefore, withdrawal of the above rejections is respectfully requested.

Turning to the prior art rejections, the Examiner has maintained his rejection of each of the pending claims based on the citation of U.S. Patent Nos. 5,523,056 to Miller, 5,419,871 to Muszak et al. and/or 5,827,478 to Carey et al, as being anticipatory under 35 USC §102(b). Applicants again herein traverse the above rejection.

First and in order to anticipate under the Statute, each and every claimed limitation must be found in a single cited prior art reference. Those limitations that are not found in the single cited reference must be notoriously well known to those in the field of the invention.

As previously noted, Miller describes a twin rotor incubator assembly for a clinical analyzer. The incubator assembly that is described includes a pair of independently driven, vertically stacked rotors 52, 54 that are interconnected by means of an elevator assembly relative to a metering station. As sample elements are metered, the elements are brought into either of the rotors using a pusher blade. In order to move any of the sample elements between these stacked and offset rings, however, there must be a vertical component of movement in order to access the remaining rotor. Applicants herein acknowledge that a horizontal pusher blade is used in combination with a rotational element (the rotors) in order to load a sample (slide) element into a respective rotor from the elevator assembly, depending on the elevation thereof. However, and in order to move sample elements between the vertically stacked ring elements in order to "free up" space, for example in one of the rings, the slide element must first be removed from one of the rings, loaded onto the elevator assembly, raised or lowered, and then reloaded horizontally into the remaining ring. Movement does not occur exclusively along a common horizontal plane.

In the present invention, according to new Claims 62 and 63, inner and outer rings are positioned on a common horizontal plane wherein movement of sample elements is accomplished by way radial movement between radially adjacent sample

element receiving areas of the inner and outer rings, the sample element receiving areas being disposed on the common horizontal plane. Miller fails to provide rings having this structure since the rotors of that reference are vertically arranged and are not radially adjacent and clearly the nonexistence of any radially adjacent structure prevents any movement between the inner and outer rings in a manner that increases throughput and efficiency of the incubator and clinical analyzer to which the incubator is associated. Each of Claims 62 and 63 as now recited clearly require rotational and radial movement in a common horizontal plane based on the structure of the sample element receiving areas of the inner and outer rings.

Muszak et al. teaches the elevator assembly that is used in the incubator described by Miller. Applicant acknowledges that the elevator assembly does include a shuttle mechanism that permits a sample element to be loaded radially into the incubator housing into one or the other of the rotor assemblies. As noted above, however, this reference elevator fails to provide any structure or a resulting mechanism capable of radial transport along a common horizontal plane between radially adjacent sample element receiving areas that are disposed on coplanarly arranged inner and outer rings. Therefore, it is believed this reference cannot anticipate either of Claims 62 or 63 under the Statute. Claims 3, 5-22 and 56-59 are also believed to be allowable for the same reasons.

Carey et al. describes an incubator assembly that is used to handle multiple assays in an immunoassay clinical analyzer. The incubator includes a housing having a single cuvette ring that includes a plurality of circumferential slots, each sized for receiving a cuvette. The cuvette ring is disposed above a magnet ring used to drive the cuvette ring. The cuvette ring is driven radially so as to pass a plurality of stations, including read stations. In addition, a number of stations are disposed outside of the incubator housing as used to dispense reagents, wash fluids, and perform other assay reaction steps. This incubator also includes an elevator assembly, as described at col 18, lines 56-67, wherein a cuvette can be lifted from a slot to permit a new cuvette to be added to take a now empty slot in the cuvette ring.

According to the present invention, and specifically amended Claims 62 and 63, an inner ring and an outer ring each arranged concentrically to one another are disposed along a common horizontal plane, the rings including respective first and second pluralities of sample element receiving areas disposed circumferentially thereupon. Moreover, the first and second pluralities of sample element receiving areas are disposed in adjacent relation radially such that sample elements can be moved between the inner and outer rings on the common horizontal plane.

The inner and outer rings are capable of rotational movement using at least one drive mechanism and the incubator includes at least one sample element shuttle mechanism that is disposed adjacent to the incubator wherein the at least one shuttle mechanism enables radial movement of at least one sample element between slide element receiving areas of the inner and outer rings along the common horizontal plane so as to increase the throughput of the incubator.

At least one shuttle mechanism is included for driving at least one sample element in the radial direction so as to either load elements into one of the pluralities of sample element receiving areas. As shown in Figs. 10-12 of the present disclosure, a plurality of sample shuttle/transfer mechanisms are provided in predetermined radial positions that permit loading of a sample element into the outer ring of the assembly and further permit movement in a radial direction of sample elements between the inner and outer rings along the common horizontal plane to effect enhanced loading and unloading of the incubator, as well as testing of the elements relative to at least one read station. The movements are all made planar to one another along the common horizontal plane of the inner and outer rings.

None of the disclosed prior art either discloses or suggests a technique as described above that permits sample elements to be loaded and tested synchronously between load stations disposed on a common horizontal plane using drive mechanisms acting in different substantially orthogonal directions while on a defined common horizontal plane and particularly to permit sample elements to be driven between various load stations or between sample element receiving areas as described herein. As a result, it is believed that amended Claims 62 and 63 are

patentably distinct of any of the three cited references for the reasons proffered above. Claims 3, 5-22 and 56-59 are believed to be allowable for the same reasons since these claims are dependent thereupon. Therefore, reconsideration is respectfully requested.

Claims 3, 6, 7, 11, 14-22, and 56-59 have been amended in order to comport with the language of amended Claims 62 and 63. To that end, it is believed no new matter has been added.

New Claims 64-67 recite features dependent upon new Claim 62 and more specifically those relating to the plurality of shuttle mechanisms being disposed at predetermined circumferential locations in relation to the inner and outer rings (Claims 64-66). Claim 67 recites that the inner and outer rings can be concentrically mounted relative to a center axis. Support is found, for example, at Figs. 10-12 of the instant application for Claims 64-66 and Fig. 3 provides support for Claim 67. Claim 68 relates to a generic form of the incubator embodiment depicted at Fig. 2. This embodiment relates to a linear version of an incubator that includes orthogonal movement of at least two rows of slide element receiving areas in a first horizontal direction, the rows being parallel and coplanar. The incubator further includes the provision of at least one drive mechanism that acts to move slide elements between the adjacent rows in a second horizontal direction orthogonal to the first horizontal direction and also in the same or common plane; that being the plane of the rows. Additional support is found in the specification for this claim at page 8, line 8 – page 10, line 22. Claims 69-71 recite dependent features relating to this embodiment including the placement of a dump station and a read station. It is believed no new matter has been added. Examination and allowance of these claims is respectfully requested.

In summary, it is believed the above-captioned patent application is now in an allowable condition and such allowance is earnestly solicited.

If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicants' representative at the telephone number below.

The Director is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0289.

Respectfully submitted,

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